

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

DAVID JONES	*	CIVIL ACTION NO. 6:21-CV-0083
	*	
VERSUS	*	JUDGE JUNEAU
	*	
LEGACY MANAGEMENT GROUP OF	*	MAGISTRATE JUDGE CAROL B.
LOUISIANA, LLC ET AL	*	WHITEHURST
	*	

DEFENDANTS' MEMORANDUM IN OPPOSITION
TO PLAINTIFF'S MOTION TO REMAND

Defendants LEGACY MANAGEMENT GROUP OF LOUISIANA, LLC and DAVID LALANDE
submit this Memorandum in Opposition to Plaintiff's Motion to Remand.

GOLD, WEEMS, BRUSER, SUES & RUNDELL

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1. **Exhibit A** - Memorandum Ruling in *Rachal v. Natchitoches Nursing & Rehab Center LLC*, Civil Docket No. 1:21-CV-00334 (W.D. La. April 30, 2021)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

DAVID JONES	*	CIVIL ACTION NO. 6:21-CV-0083
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VERSUS	*	JUDGE JUNEAU
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LEGACY MANAGEMENT GROUP OF	*	MAGISTRATE JUDGE CAROL B.
LOUISIANA, LLC ET AL	*	WHITEHURST
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DEFENDANTS' MEMORANDUM IN OPPOSITION
TO PLAINTIFF'S MOTION TO REMAND

MAY IT PLEASE THE COURT:

Defendants LEGACY MANAGEMENT GROUP OF LOUISIANA, LLC ("Legacy") and DAVID LALANDE ("Lalande") (together, the "Defendants") submit the instant memorandum in opposition to Plaintiff's Motion to Remand (R. Doc. 10). This Court should deny Plaintiff's Motion to Remand for the following reasons:

INTRODUCTION

Plaintiff has filed a Motion to Remand this case to state court, arguing that the PREP Act does not apply and that removal to this Honorable Court is not proper. Plaintiff, however, has too narrowly construed the PREP Act and has incorrectly stated that it does not apply to the allegations and claims he has asserted against Defendants. The basis for removal in this case is the doctrine of complete preemption, which provides an exception to the well-pleaded complaint rule. Because Plaintiff has asserted purportedly state law claims that fall within the purview of the PREP Act, these claims are completely preempted. Removal is therefore proper as this Court has jurisdiction over this matter. 28 U.S.C. § 1331; 28 U.S.C. § 1441. As such,

Plaintiff's Motion to Remand should be denied.

LAW & ARGUMENT

I. The Petition Is Removable Based on Complete Preemption and the *Grable* Doctrine.

Plaintiff argues extensively in his Memorandum in Support that his claims are not removable based on the well-pleaded complaint rule. However, as Plaintiff acknowledges, the well-pleaded complaint rule is inapplicable in circumstances where complete preemption exists. *See, e.g., Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 8 (2003). Here, the text of the PREP Act, the relevant guidance from the Department of Health and Human Services, and the only relevant case law from the United States District Court for the Western District of Louisiana all indicate that complete preemption does apply here.

A. The Declaration of the Secretary of Health and Human Services and All Advisory Opinions Incorporated Therein Establish that the PREP Act is a Complete Preemption Statute, and HHS Guidance Is Entitled to *Chevron* Deference.

On May 17, 2020, the Secretary of Health and Human Services issued a "Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19." (R. Doc. 6-2.) This Declaration has been amended seven times, including the crucial Fourth Amendment to the Declaration. (R. Doc. 6-5.) Further, the Office of General Counsel for the HHS Secretary has issued six advisory opinions clarifying the Declaration, as amended (the "Advisory Opinions"). (*See, e.g.*, R. Docs. 6-7, 6-8, 6-9, and 6-10). In establishing that the PREP Act provides for complete preemption, which provides the basis for federal question jurisdiction, (*see, e.g., Wright v. Louisiana Corrugated Prods., LLC*, 59 F.Supp.3d 767,

775 (W.D. La. 2014)), it is important to first establish that the Declaration, as amended, and the Advisory Opinions are entitled to deference.

An agency's statutory construction is given "controlling weight" deference when Congress explicitly delegates that authority to an agency. *Chevron, U.S.A., Inc. v. Natural Resources Defense, Inc.*, 467 U.S. 837, 843–44 (1984); *Mead Corp.*, 533 U.S. at 231 (2001)(stating notice-and-comment rulemaking is not a prerequisite to *Chevron* deference); *Cable & Telecommunications Ass'n v. Brand X Internet Services*, 545 U.S. 967, 980 (2005)("Chevron requires [deference] to an agency's construction, even if it differs from what the court believes to be the best interpretation..."); *see also* §247d-6d(b)(9)(requiring only reports to Congress, negating a notice-and-comment requirement).

The PREP Act **specifically delegates** authority to the Secretary to "make a declaration, through publication in the Federal Register, recommending, **under conditions as the Secretary may specify**, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures..." 42 U.S.C.A. § 247d-6d(b)(1). Similarly, under the same statute, Congress has authorized the Secretary to "amend any portion of a declaration under paragraph (1)." 42 U.S.C.A. § 247d-6d(b)(4). Moreover, the Secretary has, through the Congressionally-delegated authority to issue a declaration, **incorporated the Advisory Opinions** of the Office of General Counsel into the Declaration itself. The Fourth Amendment to the Declaration Under the PREP Act states, "the Declaration ***must be construed in accordance with the Department of Health and Human Services (HHS) Office of the General Counsel (OGC) Advisory Opinions...***" and that the Declaration "incorporates the Advisory Opinions for that purpose." Fourth Amended Declaration, 85 FR 79194–95 (R. Doc.

6-5) (emphasis added).

Even if this Court finds that complete *Chevron* deference is not warranted, “the Supreme Court has made clear that courts are not faced with an option of complete deference or none at all.” *Garcia v. Welltower OpCo Grp. LLC*, No. SACV2002250JVSKEsx, 2021 WL 492581, at *8 (C.D. Cal. Feb. 10, 2021) (citing *Reno v. Koray*, 515 U.S. 50, 61 (1995) (according “some deference” to an interpretive rule that “do[es] not require notice and comment”); *Martin v. Occupational Safety and Health Review Comm’n*, 499 U.S. 144, 157 (1991) (“some weight” is due to informal interpretations though not “the same deference as norms that derive from the exercise of ... delegated lawmaking powers”)).

Accordingly, for these reasons, the interpretations of the Declaration, as amended, and the incorporated Advisory Opinions are entitled to deference. This deference should extend to the statements of AO 21-01¹ that “The *sine qua non* of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both.” For these reasons, Defendants respectfully urge this Court to grant deference to the Declaration, as amended, and the incorporated Advisory Opinions.

Crucially, the only decision from the United States District Court for the Western District of Louisiana to address this issue determined that HHS’s interpretation of the PREP Act was entitled to deference. There, the Court concluded that “HHS’s interpretation of the

¹Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision (Jan. 8, 2021) available at: <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf> (R. Doc. 6-10.)

PREP Act and its scope [as set forth in AO 21-01] is reasonable” and warrants deference given: “(i) the PREP Act’s broad grant of authority to the HHS Secretary; (ii) the Secretary’s express incorporation of the OGC’s Advisory Opinions into the Declarations for purposes of construing the PREP Act; (iii) the complexity of the relevant statutory provisions; (iv) the technical nature of the subject matter; and (v) the need for uniformity in the judiciary’s interpretation of the PREP Act across the United States.” *Rachal v. Natchitoches Nursing & Rehab Center LLC*, Civil Docket No. 1:21-CV-00334, at pp. 11-12 (W.D. La. April 30, 2021), attached hereto as Exhibit A.

B. The Text of the PREP Act Provides for Complete Preemption

The fact that HHS has determined that the PREP Act is a complete preemption statute is sufficient to resolve the issue. However, in the interest of demonstrating that, under Fifth Circuit jurisprudence, the PREP Act is a complete preemption statute, Defendants offer the following analysis. The Fifth Circuit’s standard for complete preemption, is as follows:

(1) the statute contains a civil enforcement provision that creates a cause of action that both replaces and protects the analogous area of state law; (2) there is a specific jurisdictional grant to the federal courts for enforcement of the right; and (3) there is clear Congressional intent that claims brought under the federal law be removable...This test for complete preemption was subsequently clarified by the Supreme Court in *Beneficial National Bank v. Anderson*, 539 U.S. 1, 123 S.Ct. 2058, 156 L.Ed.2d 1 (2003), which shifted the focus of the last part of the test from Congress's intent that the claim be removable, to Congress's intent that the federal action be exclusive.

Gutierrez v. Flores, 543 F.3d 248, 252 (5th Cir. 2008).

The PREP Act does create civil enforcement provisions. In relation to the Congressionally-created “Covered Countermeasure Process Fund,” the relevant statute provides, “The remedy provided by subsection (a) [recovery under the “Covered

Countermeasure Process Fund] **shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses**, except for a proceeding under section 247d-6d of this title.” 42 U.S.C.A. § 247d-6e(d)(4) (West) (emphasis added). The aforementioned section 247d-6d provides, “a covered person shall be immune **from suit and liability under Federal and State law** with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.” 42 U.S.C.A. § 247d-6d(a)(1) (West) (emphasis added). The “the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for **an exclusive Federal cause of action** against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person.” 42 U.S.C.A. § 247d-6d(d)(1) (West) (emphasis added). Further, the PREP Act establishes a federal cause of action and a jurisdictional grant in a subsection entitled “Exclusive Federal jurisdiction” which provides, “Any action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia.” 42 U.S.C.A. § 247d-6d(e)(1) (West). These, provisions, taken together, demonstrate that the elements for complete preemption are satisfied and that Congress intended to create exclusive remedies under the PREP Act, to the exclusion of remedies under State law. Accordingly, the PREP Act, **which provides for immunity from suit and liability under Federal and State law and which creates an exclusive Federal remedy, is a *complete preemption* statute.**

The PREP Act is not the first complete preemption statute containing this structure.

The Air Transportation Safety and System Stability Act ("ATSSSA") was passed in the immediate aftermath of the September 11, 2011 terrorist attacks. 49 U.S.C.A. § 40101. Like the PREP Act, the statute created a Victim Compensation Fund to provide remedies for victims and/or their families who were killed or injured as a result of the September 11 attack. ATSSSA §§ 403, 405; limits airlines' liability for damages sustained as a result of those crashes, see id. § 408(a); created a federal cause of action as the exclusive judicial remedy for damages arising out of those crashes, see id. § 408(b)(1); and conferred exclusive jurisdiction in the federal court in the Southern District of New York (or "Southern District") of suits on that federal cause of action, see id. § 408(b)(3). The ATSSSA provides a similar framework as the PREP Act in which certain claimants must seek compensation from a Fund and other claims are heard under the exclusive jurisdiction of a particular federal court. The Second Circuit found that this language sufficiently indicated Congressional intent to completely preempted claims arising out of the September 11 plane crashes. *In re WTC Disaster Site*, 414 F.3d 352, 375 (2d Cir. 2005)(provisions establishing exclusive federal remedy bespoke intent to displace state-law remedies entirely for such damages claims, and provision granting to specific district court exclusive jurisdiction over all actions bringing any claim resulting from or relating to crashes had to be interpreted as authorizing removal of affected state actions to federal court). Like the ATSSSA, the PREP Act is a complete preemption statute.

C. The Only Jurisprudence from the United States District Court for the Western District of Louisiana Confirms that the PREP Act Is a Complete Preemption Statute.

As shown above, the HHS guidance and the text of the PREP Act provide for complete preemption. However, to further demonstrate that the PREP Act is a complete preemption

statute, jurisprudence from within United States District Court for the Western District of Louisiana recently established that the PREP act is a complete preemption statute. *See* Memorandum Ruling in *Rachal v. Natchitoches Nursing & Rehab Center LLC*, Civil Docket No. 1:21-CV-00334 (W.D. La. April 30, 2021). Although Plaintiff cites multiple erroneously-decided federal cases from other district courts across the nation, the only jurisprudence from **this** District establishes that the PREP Act is a complete preemption statute. Further, the mere fact that multiple district courts have ruled in a particular direction is not necessarily determinative. Regarding the above-cited ATSSSA, it was not until after the district court erroneously remanded 26 cases that the Second Circuit finally confirmed federal removal jurisdiction over all claims for injuries “related to” the 9/11 attacks based on the broad preemptive language of ATSSSA and the exclusive federal remedy for claims, even if pled in state law.

Notably, the Court in *Rachal* compared the PREP Act to the Air Transportation Safety and System Stabilization Act of 2001 and concluded that the PREP Act ***conferred exclusive federal jurisdiction*** for claims that fall within its purview. The *Rachal* opinion confirms that the PREP Act’s immunity, its sole federal cause of action, and its complete preemption apply to allegations “for anything ‘relating to’ the administration of covered countermeasures”, similar to those allegations made by Plaintiffs in the instant case. The narrow interpretations of the PREP Act urged by earlier district court decisions have been undermined by subsequent HHS Advisory Opinions and Amendments to HHS’s Declaration. In *Rachal*, the Court held that the PREP Act is a complete preemption statute because the PREP Act “contains each of” the following “elements as to claims falling within its scope”:

(1) the statute contains a civil enforcement provision that creates a cause of action that both replaces and protects the analogous area of state law; (2) there is a

specific jurisdictional grant to the federal courts for enforcement of the right; and (3) there is a clear Congressional intent that claims brought under the federal law be exclusive.

Rachal v. Natchitoches Nursing & Rehab Center LLC, Civil Docket No. 1:21-CV-00334 (W.D. La. April 30, 2021) at n.3 (citing *PCI Transp., Inc. v. Fort Worth & W. R.R. Co.*, 418 F.3d 535, 544 (5th Cir. 2005)).

Here, as demonstrated below, Plaintiff's claims fall under the PREP Act. However, to the extent that this Court has any questions as to whether these claims are within the purview of the statute, the Court should follow the approach taken by the *Rachal* Court and direct the parties to engage in a limited period of jurisdictional discovery and then brief the jurisdictional issue at the conclusion of this time-limited discovery period.

D. Plaintiff's Petition is Removable Based on the *Grable* Doctrine.

As established above, the Declaration, as amended, is entitled to deference. In the Fourth Amendment to the Declaration, the Secretary explains that, because there are substantial federal legal and policy issues at stake, jurisdiction is proper under the *Grable* doctrine. The Fourth Amendment to the Declaration states,

The Secretary makes explicit in Section XI that there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mfg.*, 545 U.S. 308 (2005), in having a ***unified, whole-of-nation response*** to the COVID-19 pandemic among federal, state, local, and private-sector entities...Thus, there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mfg.*, 545 U.S. 308 (2005), in having a uniform interpretation of the PREP Act.

85 Fed. Reg. 79190-01 (R. Doc. 6-5) (emphasis added). Accordingly, this doctrine provides yet another basis for this Court's jurisdiction in this matter.

II. The Petition is Removable Because Plaintiff's Claims Fall Within the Scope of the PREP Act

A. The PREP Act Applies Because Defendants Are “Covered Persons” Under the Act.

Plaintiff's own allegations establish Defendants as “covered persons” as defined by 42 U.S.C.A. § 247d-6d(i)(2)(B). In fact, as more fully explained below, Defendants satisfy the definitions of both a “program planner” and a “qualified person.”

1. *Defendants Are “Qualified Persons” under the PREP Act*

Under the PREP Act, a “qualified person who prescribed, administered, or dispensed” the countermeasure at issue is considered a “covered person.” The term “qualified person” includes: a) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or b) a person within a category of persons so identified in a declaration by the Secretary. 42 U.S.C.A. § 247d-6d(i)(8).² Clearly, Legacy as a long term care facility meets the above requirements. Since Lalande was the administrator of Legacy at the time of the events referenced in the Petition, Lalande is a “covered person” since he is an “official, agent or employee” of Legacy.

2. *Defendants Are “Program Planners” under the PREP Act*

The PREP Act similarly provides immunity for “program planners.” The Act defines a “program planner” as a person or entity who:

[S]upervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a

² “[A]n official, agent or employee of a person or entity” that meets the above requirement is included in the definition of a “covered person.” 42 U.S.C.A. § 247d-6d(i)(2)(B)(v).

qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with [the Secretary's declaration]. 42 U.S.C.A. § 247d-6d(i)(6).

Importantly, a "private sector employer or community group or other 'person' can be a program planner when it carries out the described activities." 85 Fed Reg. at 15199, *see* R. Doc. 6-2. It is clear that Legacy, a licensed long term skilled nursing facility, falls under the above criteria. In the context of long term care facilities, like Legacy, the administration and distribution of covered countermeasures is included in their infection control program against COVID-19. Legacy provided a facility to administer, use, and distribute such countermeasures. Legacy and Lalande supervised and administered an infection control program using covered countermeasures, which included symptom screening for all residents and staff, diagnostic testing for COVID-19, and the use of approved PPE, such as masks, gloves, and gowns.

B. The PREP Act Applies Because Plaintiff's Claims "Relate to" the "Administration" of a Covered Countermeasure.

1. *The General Standard Under the PREP Act.*

In his Motion to Remand, Plaintiff argues extensively that he does not state, in his Petition, that a covered countermeasure caused Ms. Jones to contract COVID-19 and ultimately pass away. However, the applicability of the PREP Act is focused on whether the entirety of the Plaintiff's claim "relates to" the administration of covered countermeasure. Thus, Plaintiff cannot merely isolate some alleged actions or inactions when making a claim for wrongful death as the result of contracting COVID-19. The Defendant's use and administration of covered countermeasures will necessarily be involved in determining whether Defendants are liable for or caused Ms. Jones' death.

Further, the Fifth Circuit has explained that, in cases of complete preemption, the “artful pleading doctrine” provides that “even though the plaintiff has artfully avoided any suggestion of a federal issue, removal is not defeated by the plaintiff’s pleading skills in hiding [a] federal question.” *Roland v. Green*, 675 F.3d 503, 520 (5th Cir. 2012), *aff’d sub nom. Chadbourne & Parke LLP v. Troice*, 571 U.S. 377, 134 S. Ct. 1058, 188 L. Ed. 2d 88 (2014) (citing *Bernhard v. Whitney Nat’l Bank*, 523 F.3d 546, 551 (5th Cir.2008)).

The standard under the PREP Act is that immunity applies when a plaintiff’s ***claim for loss*** relates to and has a causal relationship with the administration of a covered countermeasure. *See* 42 U.S.C.A. § 247d-6d(a)(1); 42 U.S.C.A. § 247d-6d(a)(2)(B). “Loss” under the PREP Act specifically includes death. *See* 42 U.S.C.A. § 247d-6d(a)(2)(A). Here, Plaintiff has asserted a survival action and a wrongful death claim based on the death of Ms. Jones from COVID-19. If Ms. Jones’ contracting and death from COVID-19 was potentially related to and caused by the administration of a covered countermeasure, the PREP Act is necessarily implicated.

Plaintiff’s claims regarding a nursing home patient contracting COVID-19 involve activities and decisions directly related to the delivery, distribution, and dispensing of countermeasures to recipients and the management and operation of Legacy’s covered countermeasures program, including decisions as to how best to engage, create, and implicate infection control policies in addition to optimizing supplies of PPE and utilizing COVID-19 testing kits in light of known regional and national shortages at the time. As set forth in the initial Declaration and as confirmed in the Fourth Amendment to the Declaration, the broad definition of “administration of a covered countermeasure” encompasses Defendants’ plans and decisions

with respect to how best to utilize and optimize supplies of PPE and COVID-19 testing kits, and whether and when the use of such countermeasures is appropriate.

The Fourth Amendment to the Declaration specifically states,

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, **or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for the purpose of distributing and dispensing countermeasures.**

85 Fed. Reg. 79197 (R. Doc. 6-5) (emphasis added).

Similarly, the Declaration clarifies,

[T]he Act precludes a liability claim **relating to the management and operation of a countermeasure distribution program** or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

85 Fed. Reg. 15200 (R. Doc. 6-2) (emphasis added).

Accordingly, if Plaintiff's claims are causally related to "activities and decisions" relating to the delivery of countermeasures, the "management and operation" of a countermeasure program, or "management and operation" of locations for the purpose of distributing countermeasures, Plaintiff's claims relate to the "administration" of covered countermeasures and thus fall within the scope of the PREP Act. Further, AO 21-01 clarifies that "decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning, and is expressly covered by the PREP Act." (AO 21-01, p. 4.)

Only "complete nonfeasance, where 'defendant's culpability is the result of its failure to

make any decisions whatsoever, thereby abandoning its duty to act as a program planner or other covered person,' would complete preemption not apply." *Rachal v. Natchitoches Nursing & Rehab Center LLC*, Civil Docket No. 1:21-CV-00334 (W.D. La. April 30, 2021) (citing AO 21-01). Here, the Petition does ***not*** allege complete nonfeasance. Instead, the Petition alleges that Legacy "encouraged employees to wash their hands and sanitize areas of the facility" (*Id.* at ¶ 35), "***chose*** to continue to operate in much the same way it always had--albeit with slightly more hand-washing" (Petition, R. Doc. 1-2, ¶ 38) (emphasis added), "All of Plaintiff's claims arise from Legacy Nursing Home's ***choice*** to disregard common sense procedures or to have physical infrastructure in place to prevent residents from catching Coronavirus" (*Id.* at ¶ 58), "willfully disregarded guidelines" (*Id.* at ¶ 60), and "cho[se] to continue admitting residents" (*Id.* at ¶ 60(N)). Clearly, the Petition alleges that Legacy made decisions rather than "fail[ing] to make any decisions whatsoever" as would be required to show complete nonfeasance. Similarly, the Petition alleges that Lalande "cho[se] to continue admitting residents..." (*Id.* at ¶ 62(H).) These decisions relate intrinsically to Defendants' function as program planners and to Defendants' management and operation of a countermeasure program which involved the administration of covered countermeasures. Accordingly, Plaintiff's allegations place at issue Defendants' engagement in the administration and use of several categories of "covered countermeasures" described below.

2. Definition of Covered Countermeasures

The PREP Act defines "covered countermeasure" to include, inter alia, "qualified pandemic or epidemic products," as well as "drugs, biological products or devices authorized for investigational or emergency use," or a "respiratory protective device." *See* 42 U.S.C.A. § 247d-

6d(i)(1), (8). Indeed, Advisory Opinion 20-04 recognizes that “[t]he number of products used for COVID-19 that are approved, licensed, or cleared are too numerous to list.”³

Additionally, the Declaration defines “covered countermeasure” as “any antiviral, any other drug, any biologic, any diagnostic, any other device . . . used to treat, diagnose, cure, prevent, or mitigate COVID-19 . . . or any device used in the administration of any such product” provided such countermeasure fits into at least one of the categories set forth under the PREP Act: “qualified pandemic or epidemic products”; “drugs,” “biological products,” and “devices” authorized for emergency use under the FD&C Act; or “respiratory protective devices.” 42 U.S.C.A. § 247d-6d(i)(1)§§; 85 Fed. Reg. at 15202. The April 2020 OGC Letter explains that for immunity to attach, the “drug,” “biological product,” or “device”: (1) must be used for COVID-19; and (2) must be (a) approved, licensed, or cleared by the FDA, (b) authorized under the EUA [Emergency Use Authorization], (c) described in an EUI [Emergency Use Instruction], or (d) used under either an Investigational New Drug (IND) application or an Investigational Device Exemption (IDE)⁴.

3. *Plaintiff's Claims for Loss Relate to the Administration of Multiple Covered Countermeasures*

a. Personal Protective Equipment (Masks, Gloves, Gowns)

³The Advisory Opinion cites to lists of medical devices and therapeutics that are covered by EUAs. See U.S. Food & Drug Administration, FDA Combating COVID-19 With Medical Devices (May 4, 2020), <https://www.fda.gov/media/136702/download>. See also U.S. Food & Drug Administration, Emergency Use Authorization, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-andpolicy-framework/emergency-use-authorization#covid19euas>. See R. Doc. 6-11.

⁴See DHH Advisory Opinion 20-01 <https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf>, R. Doc. 6-7.

First, Plaintiff ***specifically alleges*** that Defendants failed to require proper PPE, including “face coverings,” “face shields,” and “protective suits or other body coverings,” while Ms. Jones was a patient at Legacy. (See Petition, R. Doc. 1-2, ¶¶ 43-45.) PPE is identified as a covered countermeasure through March 2020 federal legislation. See Pub. Law. No. 115-127, Sec. 6005.

Additionally, the FDA has included numerous categories of PPE in their Emergency Use Authorizations related to COVID-19.⁵ Specifically, the Petition alleges:

Legacy Nursing Home did not require or encourage individuals to wear face coverings in the leadup to Hazel's death. ...Legacy Nursing Home did not require or encourage individuals to wear face shields to protect from COVID-19 droplets or particles in the leadup to Hazel's death. ...Legacy Nursing Home did not require or encourage individuals to wear protective suits or other body coverings in the leadup to Hazel's death.

(See Petition, R. Doc. 1-2, ¶¶ 43-45.) The Petition also alleged that Legacy and Lalande failed to implement “face covering requirements”. (*Id.* at ¶¶ 60(O), 62(I).) These allegations are all factually incorrect—PPE was being used by Defendants to prevent the spread of COVID-19 at the time of the events described in the Petition. However, although these allegations are erroneous, the allegations are all related to Plaintiff’s claims arising out of Ms. Jones’ death from COVID-19.

b. Diagnostic Devices

Plaintiff’s allegations in the Petition also indicate that Defendants utilized diagnostic testing for COVID-19 at Legacy by claiming that Legacy advised David that Hazel had COVID-19 (in addition to transferring the patient to a separate facility following a COVID-19 positive result). (See Petition, R. Doc. 1-2, ¶ 55.) The Declaration identifies “any . . . diagnostic, any other device, or any vaccine, used to treat diagnose, cure, prevent, or mitigate COVID-19 . . .” provided

⁵See U.S. Food & Drug Administration, FDA Combating COVID-19 With Medical Devices (November 24, 2020), <https://www.fda.gov/media/136702/download>.

such countermeasure fits into at least one of the categories set forth under the PREP Act. 42 U.S.C.A. § 247d-6d(i)(1); 85 Fed. Reg. at 15202. To date, a very large number of diagnostic tests for use in detecting or preventing the spread of COVID-19 have been approved, licensed, or cleared by the FDA, or subject to a EUA.⁶ The use (or allegedly negligent use or non-use) of diagnostic testing constitutes a covered countermeasure. It is implicit in the allegations of the Petition that such covered countermeasure was administered by Legacy to Ms. Jones.

c. Other Covered Countermeasures Part of Infection Control Program

Plaintiff also alleges that his claims arise from Legacy's purported "choice to disregard common sense procedures" and failure to have "physical infrastructure" in place to "prevent residents from catching the Coronavirus". (Petition, R. Doc. 1-2, ¶ 58.) Further, the Petition for Damages alleges that Legacy "encouraged employees to wash their hands and sanitize areas of the facility" but alleges that Legacy and Lalande failed to implement other protocols to stop the spread of Coronavirus. (Petition, R. Doc. 1-2, ¶ 35.) By doing so, Plaintiff references part of Legacy's infection control protocol which was in place. Thus, per Plaintiff's own allegations, Legacy had an infection control program in place, which involved decisions regarding the allocation, administration, and use of covered countermeasures thereby triggering immunity under the PREP Act. (See AO 21-01). The Plaintiff's allegations further show Defendants' attempt to comply with applicable guidance from CMS and CDC.⁷ See also, *Gilbert Garcia v. Welltower*

⁶US FDA, In Vitro Diagnostics EUAs, <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>.

⁷Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings (March 19, 2020) <https://www.esrdnetwork.org/sites/default/files/Infection%20and%20>

OpCo Group, LLC, No. 8:20-cv-02250-JVS-KESx (C.D. Cal. Feb. 10, 2021). At the time Ms. Jones contracted COVID-19, Legacy followed this guidance in their programs and procedures which were directly linked to countermeasure use and conservation.⁸

Notably, the Declaration also protects omissions or non-use by covered persons, including those which may be caused by shortages or delays in countermeasure deployment:

Where there are limited Covered Countermeasures, not administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute “relating to . . . the administration to . . . an individual” under 42 U.S.C. 247d-6d . . . [such as] when [t]he person in the vulnerable population was able to receive the vaccine only because it was not administered to the person in the less-vulnerable population. Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority’s directive, can fall within the PREP Act and this Declaration’s liability protections.”

85 Fed. Reg. 79190. (R. Doc. 6-2). For these reasons, and as further explained above, “administration” may include decisions and actions, including reasonable choices, involving how covered countermeasures are used, allocated, or dispensed. This is exactly what Legacy was doing when it developed and administered their infection control program for COVID-19. Such non-physical “administrations” apply here, where Plaintiff alleges injuries stemming from

Prevention%20-%20CDC.pdf (providing guidance regarding the handling of patients with COVID-19 in a healthcare setting. The guidance also discusses the shortages of PPE across the country and the guide indicates that the timeline for return of routine PPE levels of “unknown.”). See R. Doc. 6-14.

⁸See also e.g., SMC COVID-19 Long-Term Care Facility Guidance (April 2, 2020), <https://www.cms.gov/files/document/4220-covid-19-long-term-care-facility-guidance.pdf> (guidance regarding infection control and use/conservation of PPE. Long term care facilities were recommended to cohort residents based on status), R. Doc. 6-15; and Responding to Coronavirus (COVID-19) in Nursing Homes, (April 30, 2020) <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-responding.html>. See R. Doc. 6-16.

decisions resulting in alleged omissions or inaction that directly relate to covered countermeasures at Legacy. (See Petition, R. Doc. 1-2, ¶¶ 43-45). Plaintiff alleges that, but-for the Defendants' decisions and administration of the infection control programs, including the use of PPE when possible, sanitizing, screening for symptoms, placing residents in quarantine, etc., Ms. Jones would not have contracted COVID-19 and died. Accordingly, Plaintiff's purported injuries "relate to" Defendants' administration of covered countermeasures triggering PREP Act immunity.

Even if it can be argued that the Petition did not expressly allege that the Defendants were "administering," "using," or "distributing" countermeasures, plaintiff's allegations certainly place these activities at issue. Plaintiff's allegations implicate all activities defendants took with respect to infection control, such as failure to place restrictions on entry, lack of protocols for screening staff and residents, failure to place residents in isolation or quarantine, failure to socially distance residents, and/or failure to implement common sense advices such as social distancing, face covering requirements, monitoring symptoms, and temperature checks. Plaintiff's failure to mention the use of PPEs or testing is all the more glaring when considering that the use of such countermeasures were some of the only ways to prevent the spread of COVID-19 at the time of the events described in the Petition. Thus, Plaintiff challenges how Defendants "administered", "used", or "distributed" covered countermeasures, i.e. screening, testing, PPE to respond to the COVID-19 pandemic, all of which fall squarely within the purview of the PREP Act.

Further, even to the extent that these allegations are construed to exclude the use of products considered covered countermeasures, they would still fall under the definition of

“administration” set forth above. The Petition includes various allegations of gross negligence or willful misconduct that invoke aspects of Defendant’s “management and operation” of the facility, with all of those allegations being related to the purported spread of COVID-19 in the facility and failure to treat a patient with COVID-19, the exact “category of disease” that the Declaration was intended to address.

Therefore, if the allegations of gross negligence or willful misconduct are viewed in context, they “directly relate to” Defendant’s “management and operation” (or administration and use or non-use) of the facility during a period when covered countermeasures were being distributed and used, as well as Defendant’s “countermeasure activities” insofar as they are part of a systemic infection control program, as well as “activities and decisions” regarding the “management and operation” of the facility’s infection control practices. Further, as explained above, Plaintiff alleges that Defendants made numerous choices and decisions, all of which relate to Defendant’s infection control program. Accordingly, Plaintiff’s claims relate to and necessarily involve an analysis of Defendants’ administration of covered countermeasures, including Defendants’ “activities,” “decisions,” “management,” and “operation” of a countermeasure program.

4. *The PREP Act Applies to Cases of Inaction in Certain Circumstances.*

Notwithstanding Plaintiff’s claims to the contrary, the PREP Act applies to cases of *inaction* in certain circumstances. AO 21-01 explains that certain inaction related to the administration of a covered countermeasure falls under the PREP Act. *See also Anson v. HCP Prairie Vill. KS OPCO LLC*, No. 20-2346-DDC-JPO, 2021 WL 308156, at *10 (D. Kan. Jan. 29, 2021) (“As explained above, in theory, certain inaction claims could trigger the PREP Act.”);

Lyons v. Cucumber Holdings, LLC, No. CV2010571JFWJPRX, 2021 WL 364640, at *4 (C.D. Cal. Feb. 3, 2021) (“Although the HHS Secretary's December 3, 2020 Amendment makes clear that an ‘inaction claim’ is not necessarily beyond the scope of the PREP Act, such claims only fall under the scope of the PREP Act where: (1) there are limited covered countermeasures; and (2) there was a failure to administer a covered countermeasure to one individual because it was administered to another individual.”); *Stone v. Long Beach Healthcare Ctr., LLC*, No. CV 21-326-JFW(PVCX), 2021 WL 1163572, at *4 (C.D. Cal. Mar. 26, 2021).

Further, the Fourth Amendment addressed this same issue and likewise concluded that the PREP Act can apply to *not* administering a covered countermeasure,

Where there are limited Covered Countermeasures, *not* administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute “relating to . . . the administration to . . . an individual” under 42 U.S.C. 247d-6d. For example, consider a situation where there is only one dose of a COVID-19 vaccine, and a person in a vulnerable population and a person in a less vulnerable population both request it from a healthcare professional. In that situation, the healthcare professional administers the one dose to the person who is more vulnerable to COVID-19. In that circumstance, the failure to administer the COVID-19 vaccine to the person in a less-vulnerable population “relat[es] to . . . the administration to” the person in a vulnerable population. The person in the vulnerable population was able to receive the vaccine only because it was not administered to the person in the less-vulnerable population. Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections.

85 Fed. Reg. 79197 (R. Doc. 6-5).

PREP Act immunity does not exclude inaction or “omissions” from its protection. In fact, the PREP Act repeatedly uses the phrase “acts or **omissions**” when describing what may rise to the level of willful misconduct - thus clearly allowing for scenarios where omissions do warrant immunity. *See* 42 U.S. Code § 247d-6d. The very first Advisory Opinion relating to the

Declaration, Advisory Opinion 20-01, supports that view, expressly noting that certain "acts or **omissions**" remain immune from suit - even outside the exception for willful misconduct. *See* Advisory Opinion 20-01 at 7 (R. Doc. 6-7).

Accordingly, the mere fact that Plaintiff frames his cause of action as based on inaction **does not** necessarily mean that the PREP Act is inapplicable. To the contrary, for the reasons stated above, if the Plaintiff's allegations of gross negligence or willful misconduct are viewed in context, they clearly "directly relate to" Defendant's "management and operation" (or administration and use or non-use) of the facility during a period when covered countermeasures were being distributed and used. Further, Plaintiff's claims relate to Defendant's "countermeasure activities" insofar as they are part of a systemic infection control protocol, as well as "activities and decisions" regarding the "management and operation" of the facility's infection control practices.

CONCLUSION

For all of the foregoing reasons, Plaintiff's Motion to Remand should be denied.

Respectfully submitted,

GOLD, WEEMS, BRUSER, SUES & RUNDELL

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 17th day of May 2021, I electronically filed the foregoing with the Clerk of Court via the CM/ECF system which will send notice of electronic filing to all known counsel of record who are participants.

/s/ Sarah Spruill Couvillon
Sarah Spruill Couvillon